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USE OF METALLIC ENDOSSEOUS IMPLANTS AS A TOOTH SUBSTITUTE

ANNUAL REPORT

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UNIVERSITY OF ILLINOIS

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CHICAGO, ILLINOIS 60680

USE OF METALLIC ENDOSSEOUS IMPLANTS AS A TOOTH SUBSTITUTE

INTRODUCTION:

OBJECTIVE

The object of the study is to evaluate the viability of an artificial metallic prosthesis as a tooth replacement when placed permanently into the jaw bone. The tooth substitute consists of two parts; (1) the root portion, a metallic implant with an open-pore system of sintered metallic fiber aggregate attached to a solid metal rod; and (2) a crown portion; the portion of metal rod that extends into the oral cavity. The root portion is buried in the bone of the mandible or maxilla and the crown portion is exposed in the oral cavity and placed in function with the opposing dentition.

BACKGROUND

An appraisal of published work in the field of dental implant reveals that the dental literature abounds with articles concerned with the use of implants. The reports are mainly of clinical procedures and not one is a scientifically-based research study. In the European group, Formiggini, (1955), wrote a number of articles, (1,2), advocating the use of metallic pins in the form of a tripod as a bridge abutment. The articles were a description of his technic and clinical observations. Chercheve, (1962), recommended the use of a metal spiral as an implant (3,4,5). His articles describe the mechanics of the clinical procedures and his clinical observations. In this country, Linkow (1966) has been the leading contributor to the literature on implants, (6,7,8,9,10,11, 12). He advocates the use of metallic blades driven into the bone to become an anchor for prosthetic appliances. A complete critical review of the literature on dental implants was completed by Nateliella in 1972. He reviewed 274 articles and found an excess of reports of clinical observations and a lack of well-controlled, documented experiments (13).

RATIONALE

The development of a viable dental implant system is necessary to provide dental practioners with an alternative type of treatment to solve their patient's clinical problems. The implant must be a tooth substitute possessing the stability and bio-compatability of a natural tooth. The implant that has been developed is bio-compatible and its configuration of a metal wire mesh-work has established stability through bony in-growth.

PROGRESS REPORT

The development of a dental implant that will serve as a permanent tooth replacement began in 1969 with the use of mongrel dogs as the experimental animal. Metal fiber aggregate implants were implanted into the root wound sockets of the extracted molar teeth of dogs (fig 1). Seventy-eight implants were placed for survival times of one week to one year. Following sacrifice, histologic evaluation was made of the specimens that consisted of the implant in a block surrounding bone and soft tissue. The evaluation showed that there was bony ingrowth into the mesh-work of the implant three weeks post-operative (fig. 2). The bone and soft tissue was shown to be compatible with the metal of the implant, titanium. There were 11 failures of the 78 implants. An implant was considered a failure when it was exfoliated and found missing or when suppuration and inflammation indicated its removal.

The next step in the research plan was to subject the implant to the forces of mastication. The experimental animal was changed to the female baboon because her dentition and masticatory movements resemble humans. Thirty animals have been used in the experiment and an average of eight implants were placed in each animal. All implants had a root portion embedded in bone and crown portion which extended into the oral cavity and covered with a plastic crown reproducing the form of a normal baboon tooth (fig 3). Each crown affixed to the implant was put in functional occlusion with the opposing natural tooth. All functioning implants were free-standing; that is not attached to an adjacent tooth.

A simplified operative procedure was developed during the progress of the experiment. It was determined early in the experiment that an immediate implant placement following tooth extraction was impractical at the present time. Although only 9 of the rejected implants were listed as immediate, many more immediate implants were attempted but not placed, usually because the buccal plate of the bone was too thin and fractured. It was found that a properly sized opening into the edentulous areas of the jaws caused less trauma and was the most successful method of placing the implant.

In the baboon experiment, the teeth were extracted and the area allowed to heal for at least four weeks. Following the healing period the animal was anesthetized with surital I.V. to effect, and given normal saline I.V. during the surgery adding surital as needed. The edentulous area to be implanted was entered with a scalpel cut along the ridge. The mucosa with the periosteum was reflected, exposing the bone. A calibrated tapered bone drill in a low speed handpiece drilled the initial opening into the bone to the necessary depth to accomodate the length of the implant selected. Normal saline solution was played on the bur during drilling. A specially made four-fluted end-mill drill machined to fit the dental handpiece was used to create an opening carefully sized to fit the implant.

A hand reamer was then used to size the opening more exactly. The implant was in intimate contact with the bone for its entire length. The drilling was always cooled with normal saline and the opening in the bone flushed with normal saline. The implant was placed in the prepared opening by hand pressure or a light tap of a mallet on the end of a seating instrument. The implant was placed so that the wire mesh-work was ½mm below the alveolar crest (fig. 4). The mucosa was repositioned and sutured with triple 0 suture. The animal was on penicillin and soft diet for six days. The successful implant was fully stabilized after four weeks and impressions were taken for the construction of plastic crowns. These crowns were cemented to the post of the implant that extends into the oral cavity and adjusted to the occlusion of the animal. The implants are x-rayed and photographed monthly to document the progress of the experiment (fig. 5). Histologic specimens demostrate bone in-growth around the wires of the implant, stabilizing it and offering resistance to displacement (fig. 6). The fibrous tissue interface between the bone and metal allows a small amount of movement without resultant bone resorption (fig. 6).

BIO-COMPATIBLE STUDIES

Three studies have been completed in determining the safety of these implants in regard to the toxic effect of the metal of the implant to the host calcified tissues. A joint investigation with ADA Health Foundation Research Institute has shown that there is no metallic ion diffused from the titanium or vitallium implants.

1. The purpose of the initial study was an attempt to evaluate by means of electron microprobe analysis, the possible migration of ions from the titanium implant to the surrounding bone and soft tissue. Following sacrifice at three, six or twelve months post-operative, blocks of bone containing the implant were prepared for histological and microprobe evaluation. The microprobe employed was Cambridge Microscan V, operating a 10 KV, beam diameter of 0.5 to 1 micron, specimens being analyzed in 0.5 micron steps for 20 seconds per step. Each line was scanned twice, at distances ranging from 30 to 90 microns at four different areas per specimen, alternating between Ti and bone. Some loose encapsulating connective tissue, 4 to 40 microns in thickness, separating the implant from trabecular bone was included in all pathways as the electron beam traversed the titanium-bone interface. In no instance could the presence of titanium be detected in either the connective tissue or adjacent reparative bone, hence, suggesting that little, if any corrosion had occured as late as 12 months post-implantation.

2. In the recent literature,[1] it was reported that by use of the electron microprobe, significant quantities of nickle and chromium corrosion products were detected in tissues immediately adjacent to vitallium endodontics stabilizers. In our second study vitallium implants were inserted in edentulous areas of the maxilla and mandible of baboons. Two baboons showing clinical signs of implant failure at 11 and 29 months post-implantation were sacrificed and block sections containing the implant were removed and prepared in cross section for detection of any corrosive activity by means of electron microprobe analysis. All specimens were polished metographically. Each specimen was scanned twice in 0.5μ steps for 20 seconds at distances ranging from 20 to 90μ at four different areas per specimen, alternating between Co, Cr, Ni and Ca as the electron beam traversed the implant host bone interface. The interface, approximately 25 microns in width contained adult connective tissue. Though tissue disruption occured during metallographic polishing procedures, no accumulation of either Co, Cr or Ni could be detected in any of the remmants. Beyond this zone of possible uncertainty, and into the host bone itself, again, there was no detectable evidence of Co, Cr and Ni ions.

3. A third study has been completed on the possible corrosion of the vitallium implant.[2] A standard mark was placed into the implant prior to implantation. This indentation was photographed at 700x using the scanning electron microscope. After being embedded in the bone for 18 months, the indentation was again photographed at 700x using the SEM and showed no evidence of corrosion.

This report covers the period from March 1, 1972 to August 31, 1975. The results of the present experiments on baboons show that 182 implants have been placed with 69 lost over an experimental period of 36 months. Eighty-two crowns were placed into occlusion. (tables 1 and 2)

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A pilot human implant study has been initiated at this time because the data accumulated by the animal study indicates the possibility of success is good, also the chance of damage to the patient is minimal. No matter how long the animal studies are prolonged, ultimately the testing of an implant in a human patient can not be answered in animals, for example, would good oral hygiene increase the success rate and does the patient experience pain following the implantation and to what extent and is it controllable. A one year pilot study in humans has been funded by the United States Army Medical Research and Development Command; terminating February 28, 1976. The first implant was placed in July of 1975 (fig. 7).

The ultimate goal of a human study is to develop a safe method of replacement of the loss of a single tooth by an artificial prosthesis which will be affixed to the bone and restore masticatory function. Such a prosthesis should be free-standing and not involve the reduction of tooth structure of the adjacent teeth as in the conventional fixed bridge prosthesis. The design of the implant used in this study is this type of replacement. It has proven successful as a free-standing artificial tooth replacement in the baboon who does not provide an ideal environment for testing its efficiency.

The pilot human study is basically designed to verify that the transfer of technics and knowledge gained in animal experimentation is reproducible in humans.

The initial experiment utilizing an implant in humans is designed to have the highest predictable success rate with minimal amount of damage in case of failure. The first use of the implant will be as a terminal abutment for a fixed bridge whose anterior abutment will be a crowned natural tooth.

The first years goal is the placement of 25 implants in patients who have their molar teeth missing in one quadrant and the remaining bicuspid tooth in a normal periodontal condition. The basic plan is to place the implant in the area of the missing second molar and construct a fixed bridge attachments with pontics replacing the missing teeth. It may be a missing molar only or a missing molar and bicuspid. These bridges will replace missing teeth equally divided between mandible and maxillae.

The patients for this experiment were selected carefully to meet certain criteria. The main criteria is that they will be available for at least five years observation. They were selected based on their history of employment and residence in the same places for extended periods of time. Other criteria was their age, general oral hygiene and evidence of dental care. It was desirable to have as wide an age range as possible to determine if age is one of the variables related to successful implantation. The other major criteria was to determine through radiographic examination if there was sufficient remaining bone and establish the position of maxillary sinuses and the mandibular canal.

Mounted study models revealed whether the size of the edentulous ridge and the occlusion of the remaining teeth would make the patient a desirable candidate for the experiment.

The initial pilot study had as its major goal to determine whether the knowledge gained in the animal experiment will produce similar results in the humans. The human patients are closely supervised so that a failure of the implant is recognized early and removal accomplished with a minimum of permanent damage. The failure is determined by radiographic evidence of bone loss, clinical signs of periodontal type pockets around the implant and pain. Following implantation, long cone x-rays using superimposed millimeter grids are used routinely to record the bone level surrounding the implant. This is correlated with the clinical examination using a periodontal probe to determine the pocket depth about the implant and clinical signs of mobility and gingival inflammation. A failure is an implant that has lost half of its bony support on x-ray, has over 4mm pocket on three of its four surfaces and has class 3 mobility. Class 3 mobility is defined as over 1mm lateral movement in a bucco-lingual direction and depressable in its socket. Continued gingival inflammation resulting in a lateral abscess will also be considered a failure. Failures are removed immediately and after healing, tooth replacement will be completed by an alternate means.

The patients with successful implant bridges will be observed for a minimum of five years. Failure patients will be observed only until healing of the implant site occurs and other prosthesis is successfully fabricated.

MATERIALS AND METHODS: HUMAN STUDY 1975

All patients were treated in the College of Dentistry of the University of Illinois. The patients were thoroughly screened with complete medical histories, dental examinations including study models and complete radiological examination. The patient is fully informed as to the exact nature of the experiment and his part in it (sample in appendix). He is required to read the printed statement explaining the entire procedure including the dangers involved and the possible damage to his oral apparatus. The statement was signed in the presence of a witness, reread and initialed by the patient. A series of large size poster colored drawings were shown to the patient depicting the step-by-step surgical procedures that was done to him. Study of the radiographs and mounted study models determine the size of the implant and the exact area to be implanted.

SURGICAL PROCEDURE

Following local anesthesia, an incision was made along the edentulous ridge over the site of the proposed implantation and the mucosa and periosteum reflected to expose the bone (fig. 8). The initial cut into the bone at the implant site is made with a tapered bone drill that is calibrated in millimeters and used in a low speed handpiece (fig. 9). The bur is cooled during the drilling with a directed flow of saline solution on the bur head. After the debris is flushed out of the cavity with saline solution, a four-fluted

end-cutting bur whose size corresponds to the implant diameter is used in the slow speed handpiece to enlarge the diameter of the hole (fig. 10). The object is to make a cylindrical hole in the bone into which the implant will fit with intimate contact between the bone and the metal of the implant through its entire length. The cut bone which is collected in the flutes of the bur is preserved for future use. The end-cutting bur is also calibrated in millimeters so that the depth of the implant site can accurately be reproduced. A hand reamer is inserted into the prepared site and rotated with hand force to assure symmetry of the hole matches that of the implant (fig. 11). When necessary, a countersinking bur is used to reduce the alveolar crest so that it is completely flat (fig. 12). The sterile implant is placed into the site with hand pressure, or with the aid of a seating tool and a light tap of a mallet. The superior surface of meshwork of the implant is to be approximately ½mm below the level of the bone when seated (fig. 13). The collected bone chips are laid over the superior surface of the implant. The mucosa is repositioned and sutured into position with triple 0 silk suture (fig. 14). The patient is given tetracycline 1½ grams per day and put on a soft diet for five days. Radiographs are taken of the implant, photographs of the implant and the implant site.

The patient is seen in a week and the sutures removed (fig. 15). Weekly visits continue for approximately four weeks until the implant is stable. Each visit the patient has an examination that includes; (1) intraoral x-rays of the implant site with a millimeter grid superimposed; (2) record pocket depth around implant; (3) record clinical symptoms of pain, inflammation and (4) record mobility of implant by attempts at lateral movements and depression by finger pressure.

The fixed bridge construction commenced as soon as the implant was stable and symptom - free. This took a minimum of four weeks post-insertion. A crown preparation was made on the most posterior of the natural teeth in the quadrant followed by impressions of the complete arch; a fixed bridge constructed with the abutments for the bridge being full crowns on the natural tooth and the implant post. The edentulous areas were restored with gold veneered pontics. The prosthesis was constructed using an anatomical articulator (fig. 16).

Following the cementation of the bridge (fig. 17), the patient was seen and examined in the forementioned manner, weekly for the first month, bi-weekly for the next three months and then monthly for the first year (fig. 18 & 19). A comprehensive review of all the data on all patients was reviewed monthly by the entire staff and any consultants as deemed necessary. Experts in the fields of periodontics, oral pathology and fixed partial prosthodontics are available for consultation.

The criteria for considering an implant a failure are the following conditions: (1) loss of 50% of the initial bone at the implant site, (2) infection and suppuration about the implant or (3) class 3 mobility. Any of these conditions can dictate the removal of the implant. The proposed careful surveillance of the patient will minimize the amount of damage to the oral structures due to an implant failure, the bridge will be cut from the anterior crown and removed. A special tool has been designed that will fit into the handpiece. It is hollow and the diameter is just wider than the implant. The cutting teeth on its inferior border will cut on any remaining bone or soft tissue from the failing implant so that the resulting defect in the bone will be minimal. The removable partial denture will be made as an alternate prosthetic replacement using the bicuspid crown as an abutment. The appliance will be made at no additional cost to the patient.

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SUMMARY OF RESULTS
(BABOON STUDY - JANUARY 1976)

The number of baboons in the colony was reduced to 19; 10 animals have died or were sacrificed.

TOTAL IMPLANTS -	183	
*Old Style -	154	
**New Style -	29	
Implants in function with crowns -	103	
Uncrowned Implants -	80	
LOST IMPLANTS -	77	(48%)
New Style -	3	(10%)
Old Style -	74	(48%)
Crowned Implants -	51 of 103	(49%)

The cause of implants being lost are numerous and impossible to pinpoint due to extended periods between animal examinations. Observations during surveys of animals indicate the following etiologic factors in order of importance.

1. A major cause of implant loss was the initial attempts to place implants immediately following tooth extractions (8 out of 9; 89%).

2. The developing of the surgical technique resulted in failures due to faulty technique.

3. Gingival inflammation caused by the baboon's natural poor oral hygiene and possible reaction of tissue to acrylic crown.

4. Traumatic occlusion and food impaction due to poor contacts.

5. Animal traumatizing implant crown by use of fingers and rubbing against bars of cage.

The high rate of success of the new design of the implants in the baboons (8 out of 9; 89%) suggested the use of these implants in the human study. The idea of the open wire meshwork in the superior surface was to promote the bony ingrowth in this area to seal off the implant post from the oral environment.

The design change did not significantly alter the manufacturing process. All the new implants were made from titanium instead of vitallium. Both metals are equally biocompatible.

*Vitallium; solid metal superior surface.
**Titanium; open meshwork superior surface.

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SUMMARY OF RESULTS
(HUMAN STUDY)

There have been 25 dental implants inserted in 23 patients for periods up to 33 weeks; as of January 27, 1976. There are 13 men and 10 women in the study with an age range from 26 to 58 years old. Eighteen implant bridges have been inserted, the longest period 26 weeks.

The gingival tissue in most of the patients appeared to be normal in appearance and texture; with a minimal gingival crevice around the implant post of less than 1mm. There are two exceptions, each had an area of swelling of the oral mucosa around the post and a drop of exudate was expressed. A culture of the exudate in one case prior to bridge placement was predominately streptococcus. The second case of swelling was after the implant bridge had been inserted over 20 weeks and the implant 28 weeks. There was present hyperplastic tissue which was removed. The histologic section of this tissue appeared to be gingival tissue with normal amount of kertinization and few cells of inflammation in the underlying connective tissue. Both patients had complete recovery within a week without reoccurrence. The etiologic factor in each case was apparently food impaction.

There has been only one implant rejected. The implant was loose in the implant site due to a mechanical failure during surgery. The implant was removed without anesthesia or pain to the patient after 21 days.

There has been a second mishap where the bridge broke at the junction of the pontic and implant crown. The gold junction broke under the forces of mastication due to an imperfect gold casting. Attempts to remove the implant crown from the post were unsuccessful and the implant post had to be cut,to remove the crown. The implant had 1mm of lateral mobility following the trauma of removing the crown but has not been rejected at this time. If the implant becomes stable, a new bridge will be constructed.

The remaining seventeen bridges are all functional with no mobility.

APPENDIX

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Contract No. DADA 17-70-C-0114

PATIENT CONSENT FORM

(IMPLANT BRIDGE PATIENT)

I, _____ having attained my twenty-first birthday, and otherwise having full capacity, to consent, do hereby volunteer to participate in an investigational study entitled: USE OF METALLIC ENDOSSEOUS IMPLANTS AS A TOOTH SUBSTITUTE under the direction of Dr. Marvin B. Weiss.

This project is to evaluate the replacement of missing teeth through the use of an artificial tooth replacement that is put permanently into the jaw bone. The artificial root will be surgically placed into an area of a missing tooth.

The method of replacing missing teeth depends on the presence or absence of other teeth to support the appliance. If teeth are present and acceptable, a fixed bridge is made which cannot be taken out of the mouth and requires grinding of at least one tooth on each side of the space. The shorter the length of the bridge the better since the supporting teeth do not have to work as hard. The fixed bridge is generally the best replacement for missing teeth since it feels like your own teeth. If a tooth is not present to support a bridge or the space is very large, or many teeth are missing a removable bridge is made which rests on the gum and bone and has metal clasps to hold onto the teeth for support. This kind of replacement requires removal for cleaning. Plastic material acts as the supporting gum to the missing area. While you will be able to eat with this appliance, it is not as good as the fixed bridge because of the cleaning required and the stress placed on the holding teeth. It is usually a cheaper method of replacement than a fixed bridge. The successful use of implant allows: a fixed bridge to be made in some cases where only a removable bridge could be placed before, grinding of teeth on only one side instead of both sides of the space; a shorter length to the fixed bridge and therefore places less stress on the supporting teeth. Therefore, there are many advantages to an implant bridge. Each situation is different and the advantages or disadvantages associated with what method of replacement is indicated in your individual case will be explained.

It should take the body approximately 4-6 weeks to accept and hold the tooth replacement. When this is successful, the replacement will be treated in a manner similar to a natural tooth. A fixed (non-removable) bridge will be accomplished at this time. The bridge will replace your missing teeth and will be attached to your natural tooth by means of a crown and to the artificial tooth replacement. The bridge will be made of gold and veneered (covered) with plastic material the color of your own teeth. The laboratory cost of the bridge work will be borne equally by the patient and University of Illinois.

The surgical procedure will consist of making an opening in the bone only large enough to receive the implant. The procedure can be accomplished using local anesthesia. It is expected that post-surgical discomfort will be minimal and consistent with that accompanying an extraction. Control of the post-operative discomfort can accomplished with routine analgesics.

Success or failure will be determined by closely supervised clinical and x-ray examinations. You will be seen at least once a week for the first 4 weeks, then once every 2 weeks for the next 3 months, then once every month until one year. Routine visits will be accomplished every four months for year 2. If the implant bridge fails during the first two years, a removable bridge will be made to replace the missing teeth at no additional cost to you. Although a removable bridge is not as functionally efficient as a fixed bridge, it is adequate for normal chewing and is esthetic. It will be necessary for you to return frequently for follow-up x-rays and examinations and it may be inconvenient. Because the number of x-rays taken are greater than normally required for the replacement of missing teeth it may be inconvenient for you to return so frequently. However, it is necessary for your well being and for the success of the experiment that you are watched carefully and we can gather the necessary data.

At the end on one year's time, a small surgical procedure will be done to look directly at the implant site. The procedure will be accomplished under a local anesthetic with no loss of tissue and a minimum of post-operative pain. It will consist of making a small opening in the soft tissue and looking at the bone underneath. This opening will be sutured closed to minimize the amount of post-operative pain.

In summary, the experiment is to evaluate a new, and what dentists consider a a more effective method of replacing lost teeth, This procedure will be done with every safeguard and medical assistance to assure you of the least amount of pain and discomfort. In case of failure of the implant bridge there is a slight chance of the supporting bony ridge getting smaller in height. When this occurs an alternate means of restoring the missing teeth, namely a removable bridge, would be made at no further expense. There is another remote possibility, that of bone infection, which would be identified through the planned frequent examinations.

The implications on my voluntary participation; the nature, duration and purpose; the methods and means by which it is to be conducted; and the inconveniences and hazards which may reasonably be expected have been explained to me by_____ _____, and are set forth above. I have been given an opportunity to ask questions concerning this investigational study, and any such questions have been answered to my full and complete satisfaction.

I understand that I may at any time during the course of this study revoke my consent, and withdraw from the study without prejudice; however, I may be requested to undergo certain further examination, if in the opinion of the attending dentist, such examinations are necessary for my health or well being.

_____

Signature Date

I was present during the explanation referred to above, as well as the Volunteer's opportunity, for question, and hereby witness his signature.

_____

Witness' Signature Date

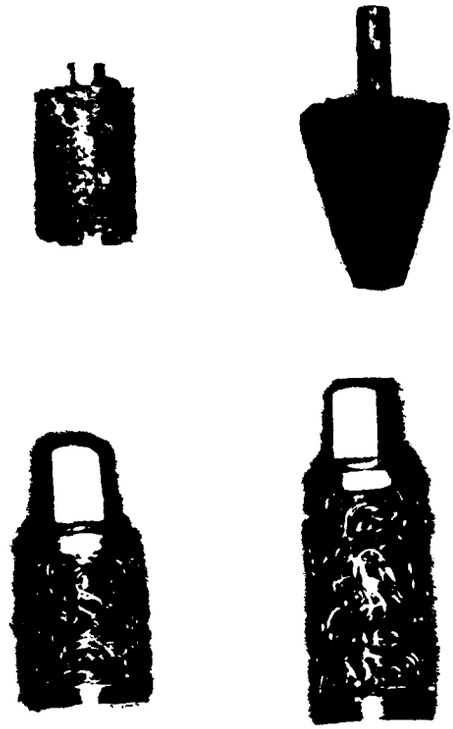


Figure 1. Various Implant Designs

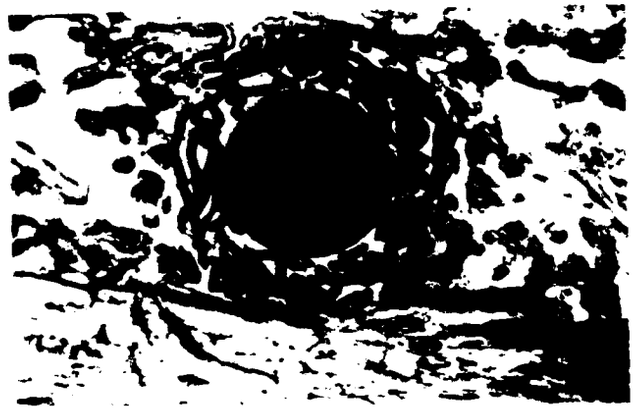


Figure 2. Cross-Section Showing Bony Ingrowth Three Weeks Post-Operative (Dog)

Figure 3. Baboon Artificial Crown

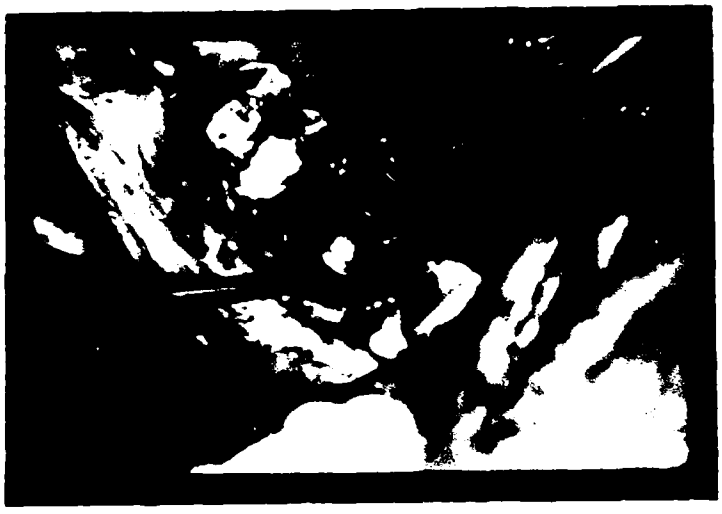


Figure 4. Implant In Baboon

Figure 5. Implant X-Ray (Baboon)

Figure 6. Bony Ingrowth (Baboon)

Figure 7. Implant In Human (X-Ray)

Figure 8. Initial Incision

Figure 9. Tapered Drill

Figure 10. End-Mill Drill

Figure 11. Hand Reamer

Figure 12. Counter-Sink Drill

Figure 13. Implant In Place

Figure 14. Sutured

Figure 15. Sutures Removed One Week Post-Operative

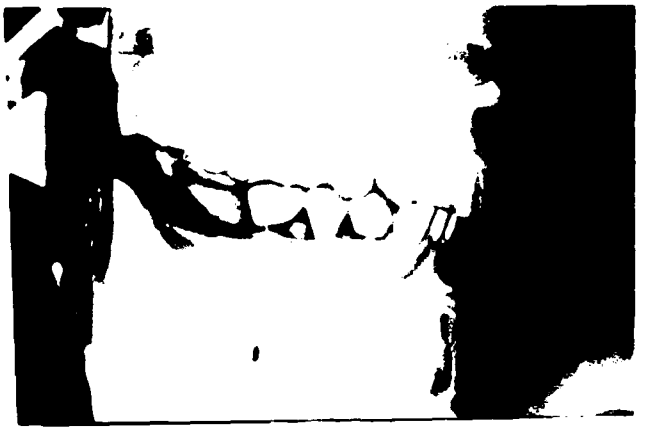


Figure 16. Implant Bridge On Model

Figure 17. Implant Bridge In Mouth

Figure 18. X-Ray Of Implant Bridge At Time Of Placement

Figure 19. X-Ray Of Implant Bridge After 2 Months

Figure 20. Implant Failure (X-Ray) Prior To Removal

Figure 21. Implant Site (X-Ray) 2 Weeks After Removal

Table 1 NUMBER OF IMPLANTS INSERTED AND SURVIVAL TIME
TOTAL NUMBER INSERTED - 182

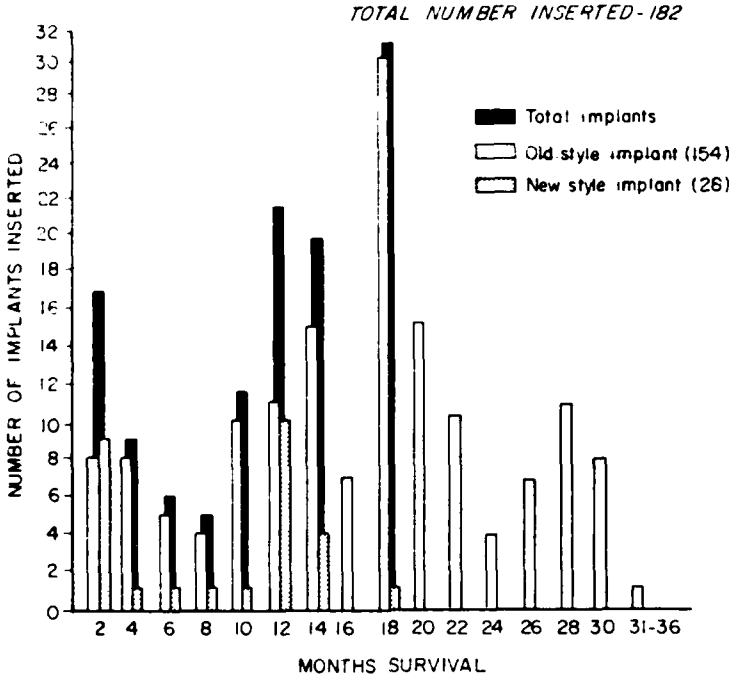
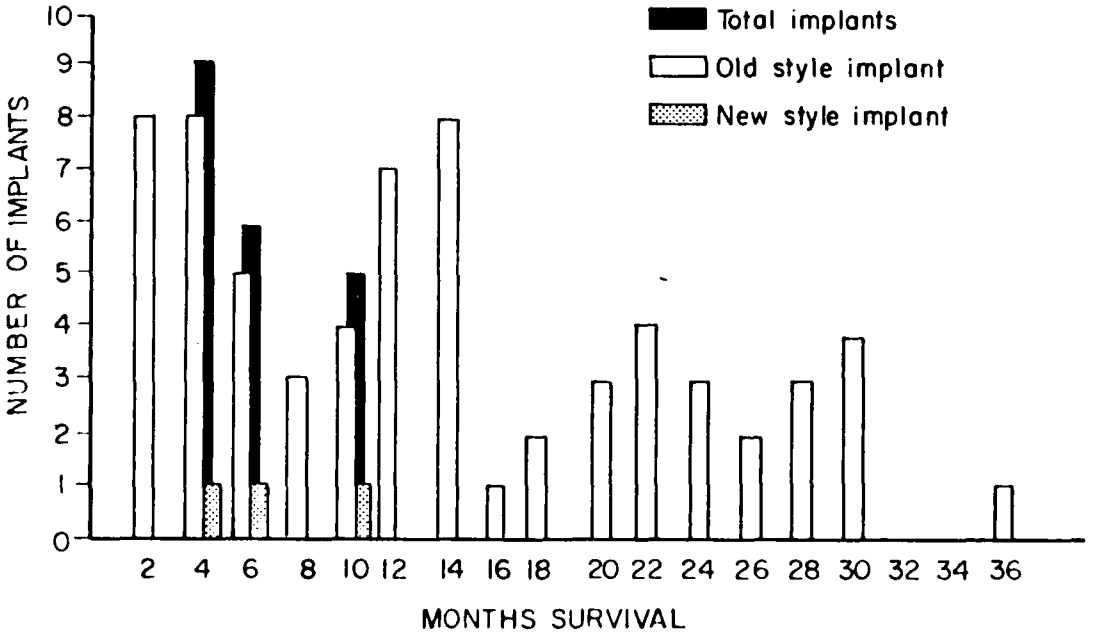


Table 2 IMPLANTS LOST *(TOTAL-69)*



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A metallic dental implant has been developed as a tooth substitute in the pilot human study. The implant is surgically inserted into the jaw bone and stabilized by bony ingrowth into its fiber metal meshwork. The post of the implant that extends into the oral cavity was used as a distal abutment for a fixed bridge. A natural tooth was used as the mesial abutment.

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